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UNITED STATES ENVIRONMENTAL PROTECTION
AGENCY
WASHINGTON, D.C. 20460



Office of Pesticide Programs

Antimicrobials Division (AD)

Thursday, January 24, 2013

MEMORANDUM

Subject: Acute Toxicity Review for EPA File Symbol: 1677-EGI
DP Barcode: D405935
Product Name: Peroxide Multi Surface Cleaner and Disinfectant

From: Ian Blackwell, Biologist *IB*
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

Through: Karen Hicks, Team Leader *KRH*
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

To: Marshall Swindell, PM 33/ *Martha Terry*
Regulatory Management Branch I
Antimicrobials Division (7510P)

Applicant: EcoLab, Inc.

FORMULATION FROM LABEL:

<u>PC Code</u>	<u>Active Ingredient(s)</u>	<u>% by wt.</u>
000595	Hydrogen peroxide	8
	<u>Other Ingredient(s)</u> :	<u>92</u>
	Total:	100

- I BACKGROUND: EcoLab, Inc., has submitted a complete set of six acute toxicity studies in support of the registration of their product, "Peroxide Multi Surface Cleaner and Disinfectant". The studies were conducted by different laboratories.

While the product is named "Peroxide Multi Surface Cleaner and Disinfectant", the test material is named "3-In-1 Disinfecting Cleaner". In order to clarify this discrepancy, the Chemistry and Toxicology Team (CTT) contacted Ted Head of EcoLab. In a 1/15/2013 email, Mr. Head stated: "... 3-in-1 Disinfecting Cleaner is identical to Multi Surface Cleaner and Disinfectant."

II RECOMMENDATIONS:

1. Each of the six submitted studies is acceptable.

The acute toxicity profile for File Symbol 1677-EGI is currently:

Study	MRID Number	Toxicity Category	Study Status
Acute Oral Toxicity	48947442	III	Acceptable
Acute Dermal Toxicity	48947441	III	Acceptable
Acute Inhalation Toxicity	48947439	III	Acceptable
Primary Eye Irritation	48947443	III	Acceptable
Primary Skin Irritation	48947444	IV	Acceptable
Dermal Sensitization	48947440	Sensitizer	Acceptable

III LABELING:

PRODUCT ID #: 001677-00238

PRODUCT NAME: Peroxide Multi Surface Cleaner and Disinfectant

PRECAUTIONARY STATEMENTS

SIGNAL WORD: CAUTION

Hazards to Humans and Domestic Animals:

Harmful if swallowed, inhaled or absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Avoid breathing spray mist. Remove and wash contaminated clothing before reuse. Avoid contact with eyes or clothing. Wear protective eyewear. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

Note: The Label Review System recommends the statement: "Wear long-sleeved shirt and long pants, socks, shoes, and chemical-resistant gloves (such as Natural Rubber, Selection Category A)." However, based upon the Label Review *Manual*, the statement is not required for this product.

First Aid:

If in eyes:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- Call a poison control center or doctor for treatment advice.

If on skin:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

If inhaled:

- Move the person to fresh air.
- If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.
- Call a poison control center or doctor for further treatment advice.

If swallowed:

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a poison control center or doctor.
- Do not give anything to an unconscious person.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

Label Created by: Ian Blackwell on 01/24/2013 Last Updated by: Ian Blackwell on 01/24/2013

DATA REVIEW FOR ACUTE ORAL TOXICITY TESTING (§ 81-1, 870.1100)

Up and Down Procedure

Product Manager: 33

MRID No.: 48947442

Reviewer: I. Blackwell

Study Completion Date: 4/16/2012

Calvert Study No.: 0406RE31.001

Testing Laboratory: Calvert Labs

Authors: René E. Vasquez, Ph.D.

Quality Assurance (40 CFR §160.12): Included

Test Material: 3-In-1 Disinfecting Cleaner. "yellow liquid"

Species: Sprague-Dawley rat

Weight: 189 to 204 grams

Age: 10 to 11 weeks

Source: Harlan

Conclusion:

1. LD₅₀ (mg/kg):
Males > 2,000 mg/kg
Females > 2,000 mg/kg
Combined > 2,000 mg/kg

2. The estimated LD₅₀ is greater than 2,000 mg/kg of body weight.

3. Tox. Category: III Classification: Acceptable

Procedure (Deviations from §81-1): None

Results:

Dosage (mg/kg)	(Number Deaths/Number Tested)		
	Males	Females	Combined
550	---	0/1	---
2,000	---	0/3	---

Observations: Brown urogenital staining, decrease body tone, piloerection, poor grooming

Gross Necropsy: No visible lesions.

DATA REVIEW FOR ACUTE DERMAL TOXICITY TESTING (§81-2, 870.1200)

Product Manager: 33
MRID No.: 48947441

Reviewer: I. Blackwell
Study Completion Date: 4/20/12
Calvert Study No.: 0422RE31.001

Testing Laboratory: Calvert Labs

Author: René E. Vasquez, Ph.D.

Quality Assurance (40 CFR §160.12): Included

Test Material: 3-In-1 Disinfecting Cleaner. "yellow liquid"

Species: Sprague-Dawley rat

Weight: 207-268 g

Age: 8-10 weeks

Source: Harlan

Summary:

1. **LD₅₀ (mg/kg):**

Males > 2,000 mg/kg b.w.
Females > 2,000 mg/kg b.w.
Combined > 2,000 mg/kg b.w.
2. The estimated LD₅₀ is greater than 2,000 mg/kg of body weight.
3. **Tox. Category:** III **Classification:** Acceptable

Procedure (Deviation From §81-2): None

Results:

Reported Mortality

DOSAGE (mg/kg)	(NUMBER DEATHS/NUMBER TESTED)		
	Males	Females	Combined
2,000	0/5	0/5	0/10

Observations: Animals appeared normal; moderate-to-severe erythema, well-defined erythema, slight to moderate edema.

Gross Necropsy Findings: The lab reported that there were no visible lesions.

DATA REVIEW FOR ACUTE INHALATION TOXICITY (§81-3, 870.1300)

Product Manager: 33

MRID No.: 48947439

Reviewer: I. Blackwell

Study Completion Date: 7/26/2012

Test Facility Study No.: 672076

Testing Laboratory: Charles River Labs

Author: Kevin Dillon

Quality Assurance (40 CFR §160.12): Included

Test Material: 3-In-1 Disinfecting Cleaner. "Clear yellow liquid"

Concentration: gravimetric= 0.59, 1.87 and 4.91 mg/L. Nose-only exposure

Species: Sprague-Dawley CRL:CD®SD rats

Weight: Males= 227-321 g

Females= 178-221 g

Age: 8-10 weeks

Source: Charles River UK Limited

Summary:

- LC₅₀ (mg/L)**
Males= $0.59 < x < 1.87$ mg/L
Females= $0.59 < x < 1.87$ mg/L
Combined= $0.59 < x < 1.87$ mg/L
- The estimated LC₅₀ is $0.59 < x < 1.87$ mg/L of air.**
- MMAD:** (See table) μm
- Toxicity Category:** **Classification:**

Procedure (Deviation From §81-3): None

Results:

Reported Mortality

Exposure Concentration	(NUMBER DEATHS/NUMBER TESTED)		
	Males	Females	Combined
0.59 mg/L	2/5	1/5	3/10
1.87 mg/L	5/5	3/5	8/10
4.91 mg/L	5/5	5/5	10/10

Chamber Atmosphere			
Dose Level	MMAD	GSD	particles < 2.9 µm
0.59 mg/L	2.28 µm	2.3935 µm	50.8%
1.87 mg/L	2.60 µm	2.3595 µm	47.55%
4.91 mg/L	3.27 µm	1.924 µm	25.05%

Chamber Environment			
	0.59 mg/L	1.87 mg/L	4.91 mg/L
Chamber Volume	20 L	40 L	40 L
Airflow (L/min.)	39	17	9
Temperature	18.5-19.1° C	21.4-22.9° C	21.5-22.0° C
Relative Humidity	66.3-90.0%	79.2-100.0%	100.0%
Nominal Concentration	9.5 mg/L	20.8 mg/L	40.7 mg/L

Clinical Observations: Irregular, shallow, labored, crackling, or slow respiration; gasping, subdued behavior, hunched posture, salivation, rolling/ high step gait, piloerection, wet/unkempt coat, head or muzzle staining, pale extremities eyes partially closed, loose feces and vocalizing.

Gross Necropsy Findings: Discoloration or foci in lungs, spongy lungs; fluid buildup in lungs, discoloration of liver, distention of G.I. tract, "abnormalities in the stomach, skin and subcutis".

DATA REVIEW FOR PRIMARY EYE IRRITATION TESTING (§81-4, 870.2400)

Product Manager: 33

MRID No.: 48947443

Reviewer: I. Blackwell

Study Completion Date: 4/17/2012

Test Facility Study No.: 20023026

Testing Laboratory: Charles River Laboratories

Author(s): Jody R. Hohenbrink, MS

Quality Assurance (40 CFR §160.12): Included

Test Material: 3-In-1 Disinfecting Cleaner. "yellow liquid"

Dosage: 0.1 mL

Species: New Zealand White rabbit

Sex: 5 males

Weight: Approx. 2.8 kg

Age: Approx 17 weeks

Source: Charles River, Quebec

Summary:

1. Toxicity Category: III
2. Classification: Acceptable

Procedure (Deviations From §81-4): None

Results:

Observations	(number "positive"/number tested)							
	Hour	Days						
	1	1	2	3	4	7	14	21
Corneal Opacity	0/3	0/3	0/3	0/3	---	---	---	---
Iritis	3/3	0/3	0/3	0/3	---	---	---	---
Conjunctivae								
Redness	3/3	0/3	0/3	0/3	---	---	---	---
Chemosis	0/3	0/3	0/3	0/3	---	---	---	---
Discharge	0/3	0/3	0/3	0/3	---	---	---	---

--- = no observations at this point

DATA REVIEW FOR SKIN IRRITATION TESTING (§81-5, 870.2500)

Product Manager: 33

MRID No.: 48947444

Reviewer: I. Blackwell

Study Completion Date: 4/17/2012

Test Facility Study No.: 20023027

Testing Laboratory: Charles River Laboratories

Study Director: Jody R. Hohenbrink, MS

Quality Assurance (40 CFR §160.12): Included

Test Material: 3-In-1 Disinfecting Cleaner. "Clear, yellow liquid"

Dosage: 0.5 mL

Species: New Zealand White rabbit

Weight: 2.6 – 2.7 kg

Age: Approx. 16 weeks

Source: Charles River Laboratories, Inc.

Summary:

1. **Toxicity Category:** IV
2. **Classification:** Acceptable

Procedure (Deviations From §81-5): None

Procedures: The lab used three different exposure time lengths: 3 minutes, 1 hour and 4 hours.

Results:

Three-Minute exposure: "Exposure to the test substance produced very slight erythema at the single test site immediately after patch removal. The dermal irritation resolved completely by the 24-hour scoring interval."

One-Hour exposure: "Exposure to the test substance produced well-defined erythema and very slight edema at the single test site immediately after patch removal. The dermal irritation resolved completely by the 48-hour scoring interval."

Four-Hour exposure: "Exposure to the test substance produced very slight erythema at 2/3 test sites, well-defined erythema at 1/3 test sites, and slight edema at 1/3 test sites by the 1-hour scoring interval. The dermal irritation resolved completely at all test sites by the 48-hour scoring interval. Additional dermal findings were limited to tape irritation outside of the test site (3/3 test sites).

DATA REVIEW FOR DERMAL SENSITIZATION TESTING (§81-6, 870.2600)

Product Manager: 33
MRID No.: 48947440

Reviewer: I. Blackwell
Study Completion Date: 4/30/2012
Calvert Study No.: 0424GE31.001

Testing Laboratory: Calvert Labs
Author: René E. Vasquez, Ph.D.

Quality Assurance (40 CFR §160.12): Included

Test Material: 3-In-1 Disinfecting Cleaner. "yellow liquid"
Positive Control Material: DNCB

Species: Hartley guinea pig
Weight: 357-488 grams
Source: Elm Hill Breeding Laboratories
Age: 5-6 weeks

Method: Buehler Method

Summary:

1. This Product is a dermal sensitizer.
2. Classification:

Procedure (Deviation From §81-6): None

Procedure:

Induction: The test material (3-In-1 Disinfecting Cleaner diluted to 75%) was applied to the test subjects in 25 mm Hill Top Chambers. The patches were occluded with rubber dental dams. The test material applications were removed after 6 hours. The positive study was conducted in the same manner using DNCB. The naïve (vehicle) control study was conducted in the same manner, but, using saline.

Challenge: Fifteen days after the last induction treatment/ exposure, the animals were challenged in the same manner as the induction treatments using 50% dilutions, but in different sites.

Results:

Induction: Twenty-four hours after induction, 6/20 test material-induced animals displayed moderate erythema, 3/20 slight erythema, and 4/20 very slight erythema.

Challenge: Twenty-four hours after challenge, 1/20 test material-induced animals displayed moderate erythema, 5/20 slight erythema, and 1/20 very slight erythema. There was no irritation at this time in the saline vehicle control or saline-treated/ test material animals. The positive control animals displayed slight erythema in 6/6 animals 48 hours after challenge.